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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,880	04/19/2004	Joel M. Blatt	BAYER 3.0-003 CONT	9880
74144 BAYER	7550	06/11/2008	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, NJ 07090			NGUYEN, BAO THUY L.	
			ART UNIT	PAPER NUMBER
			1641	
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			06/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,880

Applicant(s)

BLATT ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2008 has been entered.
2. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and/or arguments.

Claim Rejections - 35 USC § 112

3. Claims 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-60 are vague because it doesn't appear that the different reagents bind to each other, i.e. the binding relationship between the various reagents is not clearly recited. For example, part b) recites that the non-diffusively bound first reagent forms a first reaction product when contacted with a mixture of the sample and labeled indicator reagent, but it is unclear if the labeled reagent binds to the analyte in sample or if the first reagent binds to this complex or to the analytes, etc.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 51-60 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fitzpatrick et al (US 5,451,504) in light of May (WO 88/08534).

Fitzpatrick discloses a device and method comprising a pathway of three zones, a first mobilization zone (i.e. sample application zone), a second trap zone (i.e. test zone), and a third detection zone (i.e. reference zone), arranged so that the first and the third zone are spaced apart by the second zone. Labeled receptor specific for the

analytes is provided on the first zone, the second zone has immobilized ligand (that binds to the labeled reagent when analyte is not present producing a signal that is inversely proportional to the concentration of analyte), the third zone provides for detection a receptor-analyte complex which positively correlates with the presence of analyte in the sample. See column 2, lines 26-36. Fitzpatrick teaches that any arrangement that provides a series of three or more zones in communication so that liquid will move from the first zone through the second into the third zone may be used. Column 3, lines 27-37. In addition to the basic three zones, the sample pathway may also include an application zone for applying sample, and an absorbent zone which facilitates movement of the sample through the zones as well as a control zone. See column 3, lines 37-49.

With respect to claims 52, 53 and 55, Fitzpatrick teaches that the solid support may be a sheet or film with the zones arrayed sequentially along a sample pathway. Other suitable solid phase supports includes nylon, coated plastic and glass, filters, paper, membranes, etc. See column 2, lines 51-68.

With respect to claim 54, Fitzpatrick discloses the possible detection of more than one analytes and appropriate modifications therein. See column 10, lines 47-51.

With respect to claim 56, Fitzpatrick teaches the use of reagents such as antibodies, antigens, etc. See columns 5-7.

With respect to claim 57, Fitzpatrick discloses an application zone that functions as a filter for removing undesirable particles from a sample. See column 9, lines 30-32.

With respect to claim 58, Fitzpatrick teaches labels selected from colloidal gold, dye polymers, colored latex particles, or enzyme conjugated to receptors such as antibodies or antigens. See column 4, lines 26-34 and column 8, lines 30-37.

With respect to claim 59, Fitzpatrick teaches the first reagent in the trap zone is an immobilized ligand comprising an analog of the analyte. See column 7, line 3 through column 8, line 10.

With respect to claim 60, Fitzpatrick teaches that the second reagent is an immobilized binding partner (i.e. an antibody) that binds to the labeled receptor that is bound to the analyte. Detection of signal provides a positive correlation to the concentration of analyte. See column 8, line 13 through column 9, line 15.

Fitzpatrick is silent with respect to the detection of analyte concentration.

May, however, teaches a test strip similar to the instant claims and those of Fitzpatrick. May teaches a capture zone comprising an immobilized capture reagent for capturing a complex between the analyte and the labeled binding partner. May specifically teaches that the intensity of the signal from the label which becomes bound the test zone can provide a qualitative or quantitative measurement of analyte in the sample. See page 11, lines 19-27.

Since the labels used in the device and method of May are the same with the labels taught by Fitzpatrick and the instant claims, these labels would be expected to have the same inherent properties and would therefore aid in the detection of both the presence and amount of analyte in sample.

Even though Fitzpatrick does not specifically state that the detectable response in the test zone plus the detectable response in the reference zone equal a total detectable response that is substantially constant for a pre-determined range of analyte concentration, Fitzpatrick anticipates the instant claims because this wherein clause is nothing more than an intended use of the device. In other words, it does not alter the structure of the device which is taught in its entirety by Fitzpatrick. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Arguments

6. Applicant's arguments filed 12 May 2008 have been fully considered but they are not persuasive.

Applicant argues that Fitzpatrick does not teach a detectable response in its trap zone. This argument is not persuasive. Fitzpatrick teaches that the binding partner in the trap zone binds the labeled receptor when the labeled receptor is not bound to the analyte, and Fitzpatrick teaches that the label is visual and self indicating such as colored latex particle, dye polymer or colloidal gold. Thus, when the binding partners in the trap zone bind the labeled receptors, a signal is present. And, depending on the intensity of the signal from the labels, it means that either analyte is not present in the

sample or some amount is present, etc, i.e. the signal response is inversely proportional to the analyte concentration.

The argument that Fitzpatrick specifically disavows any such inversely proportional response is not persuasive because there is no evidence that this argument is true. As stated above, Fitzpatrick specifically teaches that the trap zone binds labeled receptors that are not in a complex with the analyte, therefore, an inverse relationship between any signal in the trap zone and the analyte is observed. Nowhere did Fitzpatrick specifically disavow this relationship.

The argument that Fitzpatrick teaches only the detection of a positive signal as evident that Fitzpatrick specifically disavows signals in the trap zone is not persuasive. Fitzpatrick state that a positive signal in the *detection zone (i.e. reference zone)* is psychologically satisfying versus instances when no signal in the *detection zone* means a positive test result. This is not evidence that Fitzpatrick teaches away from observing a signal in the *trap zone (i.e. test zone)*. Furthermore, "a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be lead in a direction divergent from the path that was taken by the application...[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the application." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Fitzpatrick would not have deterred the skilled artisan from making the and using the invention as claimed.

Clearly, any test strip can be adapted to detect the presence and amount of an analyte in a sample by appropriate choice and concentration of reagents as taught by Fitzpatrick in light of May.

The argument that Fitzpatrick does not teach any proportional response in its detection zone and does not disclose any inversely proportional response in its trap zone is not persuasive.

As stated above, it is clear from the teaching of Fitzpatrick that if signal is observe in the trap zone, no analyte is present in the sample. This is an inverse relationship.

The argument that Fitzpatrick does not teach that the signal from the detection zone is proportional to the analyte concentration is not persuasive. Although Fitzpatrick does not specifically teach that the observe signal provides an *amount* of the analyte, i.e. is proportion or inversely proportional, Fitzpatrick specifically teaches that the method and device of their invention is comparable with conventional ELIZA which does provide an analyte concentration, therefore, this feature is inherently present in the device of Fitzpatrick. Furthermore, the reagents taught by the instant claims, e.g. antibodies, antigens as well as the labels, e.g. particle-linked antigen or particle linked antibody, are the same as those of Fitzpatrick, therefore, the device and reagents taught by Fitzpatrick inherently possess the same characteristics as those of the instant invention.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
June 4, 2008